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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,670	01/05/2006	Thomas Gore	I-2002.025 US	4798

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,670	GORE ET AL.	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008 and 20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29,31,33-37 and 40-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28, 29, 31, 33, 34-37 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Appeal Brief

In view of the Appeal Brief filed on October 20, 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing at the end of the office action.

Response to Amendment

The amendments to the claims filed August 4, 2008 have been acknowledged and entered. Claims 28 and 34 are currently amended.

Status of the Claims

Claims 28, 29, 31, 33, 34-37 and 40-42 are pending and under examination. Claims 1-27, 30, 32 and 38-39 have been canceled.

Rejections Withdrawn

The rejection of claims 28, 30 and 32 under 35 U.S.C. 103(a) as being unpatentable over Appel et al. (4,193,990) and Appel et al. (4,193, 991) in view of Pratelli et al. (Journal of Veterinary Diagnostic Investigation, 1999, Vol. 11, pages 365-367) **is withdrawn**.

The rejection of claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appel et al. (4,193,990) and Appel et al. (4,193,991) in view of Pratelli et al. as applied to claims 28, 30 and 32 above, and further in view of Audonnet et al. (US Patent No. 6,159,477, Dec. 2000) **is withdrawn**.

The rejection of claims 28-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Appel et al. (4,193,990) and Appel et al. (4,193,991) in view of Pratelli et al. and Audonnet et al. as applied to claims 28-33 above, and further in view of Poulet et al. (Veterinary Record, 2001, Vol. 148, No. 22, pages 691-695) and Correa (Alabama Cooperative Extension System, November 2002, 7 pages) **is withdrawn**.

Applicant's arguments filed August 4, 2008 and October 20, 2008 have been fully considered and are persuasive. Previous rejections have been withdrawn. New rejections are set forth below.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28, 29, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carmichael et al. (Journal of Veterinary Diagnostic Investigation, 1994, Vol. 6, pages 165-174) and Audonnet et al. (US Patent 6,228,846, May 2001) in view of McDonald (Veterinary Medicine, March 1992, Vol. 87, No. 3, pages 223-230) and Meloen et al. (Biologicals, 2001, Vol. 29, pages 233-236).

The claimed invention is drawn to a vaccine comprising an inactivated whole Minute virus of canine (MVC), also known as Canine Parvovirus I, (CPV-1), wherein the vaccine further comprises at least one additional antigen of a Canine Herpesvirus (CHV), Canine Rotavirus (CRV), or Canine Parvovirus type 2 (CPV-2), wherein at least one additional antigen is an inactivated virus, wherein at least one additional antigen is an attenuated live virus.

Carmichael et al. (hereinafter Carmichael) teaches Minute virus of canines (MVC) is a pathogenic canine virus (Abstract and page 173, 2nd column). Carmichael teaches MVC causes respiratory illness in young pups and of transplacental infections with embryo resorption (Abstract). Carmichael also teaches approximately 50% of dogs in the United States have antibodies to MVC (Abstract). This indicated that dogs which have the antibodies have been exposed to the virus previously and survived the infection. Therefore, the antibodies protect the dogs which suggest that this is a good candidate for a vaccine based on a whole inactivated virus. However Carmichael does not teach a vaccine composition or a vaccine comprising other pathogens antigens.

Audonnet et al. (hereinafter Audonnet) teaches a vaccine formulation allowing the vaccination of dogs against a large number of infectious pathogens (col. 1, lines 31-35). Audonnet teaches the vaccine can comprise antigens from CHV and parvovirus (col. 3, lines 54-58 and col. 4, lines 3-7). Audonnet teaches the antigen provides protection against the virus of the pathogen (col. 4, lines 8-11). Audonnet teaches the vaccine can be from live or inactivated whole viruses (col. 5, lines 36-52). Audonnet also teaches the vaccine can be attenuated live virus (col. 5, lines 64-67).

McDonald teaches the goal of vaccine antigen administration is to elicit protection by humoral (antibody) immunity or cell-mediated immunity or both (page 223, 2nd col.) McDonald teaches there are three common types of vaccines: modified-live vaccines (attenuated), killed-virus vaccines (inactivated), and subunit vaccines (page 224, Vaccine basics). McDonald teaches the main advantage of a killed vaccine is its inability to revert to a virulent form and initiate disease therefore these vaccines are safer than other types of vaccines in immunosuppressed and pregnant animals, and perhaps all animals (page 225, 2nd col. 1st para.).

Meloen et al. (hereinafter Meloen) teaches two hundred years after Jenner invented vaccination, all successful efforts to design new vaccines are still based on whole attenuated or inactivated pathogens or major parts thereof (page 233, left column). Although impressive efforts have been made, these efforts never resulted in a vaccine that could match the efficacy of the classical vaccine based on inactivated virulent virus (page 233, right column). Meloen teaches inactivated virulent virus is able to induce full protection (page 234, 1st column). Meloen teaches attempts of synthetic peptide vaccines have had disappointing results however, we are on

the brink of developing new technologies (page 233, right column and page 234, right column, last paragraph).

In summary, Carmichael teaches MVC is a pathogen while Audonnet teaches dog vaccines comprising multiple antigens from pathogens and inactivated and attenuated live virus vaccines. McDonald teaches advantages of killed vaccines and safety in animals. Meloen teaches whole inactivated vaccines are still the "gold standard".

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to produce a vaccine comprising MVC. The person of ordinary skill in the art would have been motivated to make a vaccine because Carmichael teaches it is a pathogen, and reasonably would have expected success because Audonnet teaches multivalent vaccines and McDonald teaches inactivated and attenuated vaccines are preferred and they are safe.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use a whole inactivated virus vaccine because this technology is successful, has good efficacy and well known in the art as taught by Meloen. A person of ordinary skill in the art would have been motivated to use whole inactivated virus vaccine because this technology is able to induce full protection as taught by Meloen

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to produce a vaccine against a viral pathogen to protect canines. The methods of producing the vaccine are known in the art and the MVC pathogen is well documented in the art as causing respiratory illness in young pups and of transplacental infections with embryo resorption as taught by Carmichael (Abstract).

Claims 34-37 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carmichael et al. (Journal of Veterinary Diagnostic Investigation, 1994, Vol. 6, pages 165-174) and Audonnet et al. (US Patent 6,228,846, May 2001) in view of McDonald (Veterinary Medicine, March 1992, Vol. 87, No. 3, pages 223-230) as applied to claims 28, 29, 31 and 33 above, and further in view of Poulet et al. (Veterinary Record, 2001, Vol. 148, No. 22, pages 691-695) and Correa (Alabama Cooperative Extension System, November 2002, 7 pages).

The claimed invention is also drawn to a method of protecting a puppy against MVC, also known as CPV-1, comprising administering a vaccine comprising an inactivated whole MVC to a pregnant bitch prior to whelp, and administering colostrums of the bitch to at least one puppy within about 24 or 48 hours of whelp whereby maternal antibodies are transferred at a sufficiently high titer to protect the puppy from disease caused by MVC, wherein the maternal antibodies are transferred by allowing the puppy to nurse within about 24 or 48 hours, wherein the vaccine further comprises at least one additional antigen of CHV, CRV or CPV-2, wherein at least one additional antigen is an inactivated virus or an attenuated live virus.

The teachings of Carmichael, Audonnet and McDonald are described above, however they do not teach administering the vaccine to pregnant dogs.

Poulet et al. (hereinafter Poulet) teaches a method of vaccinating pregnant bitches against CHV-1 wherein the puppies were protected after nursing (Abstract).

Correa teaches the importance of puppies consuming colostrums within the first 12 to 24 hours after birth (page 6, paragraph joining columns 1 and 2). Correa also teaches that the

colostrum, mother's first milk, contains antibodies, which provide protection from infectious diseases (page 6, paragraph joining columns 1 and 2).

In summary, Carmichael teaches MVC is a pathogen while Audonnet teaches dog vaccines comprising multiple antigens from pathogens and inactivated and attenuated live virus vaccines. McDonald teaches advantages of killed vaccines and safety in pregnant animals.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to administer the vaccine to pregnant dogs. The person of ordinary skill in the art would have been motivated to give the vaccine to pregnant dogs because Correa teaches the importance of immunizing pregnant dogs to provide short-term immunity in nursing puppies, and reasonably would have expected success because Poulet teaches administering vaccines to pregnant dogs and McDonald teaches killed vaccines are safe for pregnant dogs.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to vaccinate the bitch and allow the puppies to nurse within 24 hours. The person of ordinary skill in the art would have been motivated to vaccinate the pregnant bitch because Poulet teaches the importance for survival of the puppies. The person of ordinary skill in the art would have also been motivated to allow the puppies to nurse in the first 24 hours because Correa teaches the importance of puppies receiving colostrums to absorb antibodies to protect from diseases.

Response to Arguments

Applicant's arguments with respect to the prior art teaching CPV-2 vaccines have been considered but are moot in view of the new ground(s) of rejection. Applicants emphasize that

MVC also known as CPV-1 is a different virus than CPV-2 as taught by Pratelli *et al*. Although the reference of Appel et al. does not designate CPV-1 or CPV-2 in the Patents cited, Examiner has withdrawn the rejections pursuant Applicant's arguments. Applicants allege that the reference is directed to a CPV vaccine prepared from CPV-2.

Conclusion

Due to the new grounds of rejection this action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

January 2, 2009
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648